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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,204	01/24/2001	Malcolm R. Alison	54113-8004.US01	4799
7590 11/20/2003			EXAMINER	
Perkins Coie LLP			SULLIVAN, DANIEL M	
Patent- LA			ART UNIT	
P.O Box 1208			PAPER NUMBER	
Seattle, WA 98111-1208			1636	

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/769,204		ALISON ET AL.	
	Examiner		Art Unit	
	Daniel M Sullivan		1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b)

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26,27 and 51-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 51-65 is/are allowed.
- 6) ☒ Claim(s) 26,27 and 66-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a reply to the "Amendment and Response" filed 5 September 2003 (hereinafter, 5 September Paper), which is a response to the Non-Final Office Action mailed 2 June 2003 (hereinafter 2 June Office Action). Claims 26, 27 and 51-65 were considered in the 2 June Office Action. Claims 51, 52, 54 and 56 were amended and claims 66-68 were added in the 5 September Paper. Claims 26, 27 and 51-68 are pending and under consideration.

Response to Amendment

Claim Objections

Objection to claim 51 is withdrawn

Double Patenting

Claims 26 and 27 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 6,248,725 (hereinafter '725). Applicant's willingness to file a terminal disclaimer upon allowance of the pending claims is acknowledged. The outstanding rejection will be withdrawn when the terminal disclaimer is filed.

Rejections - 35 USC § 112

Rejection of claims 51-65 under 35 U.S.C. 112, first paragraph, as lacking enablement for the full scope of the claimed subject matter is withdrawn in view of the amendment of the claims such that they are no longer directed to preventing cirrhosis of the liver.

New Grounds Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 65-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims are directed to a method for treating “a subject at risk of developing cirrhosis of the liver”. In the remarks, Applicant indicates the claims are supported throughout the specification and at page 15, lines 3-10 in particular. The passage cited teaches that the methods described can be used to prevent any of a variety liver conditions. However, nowhere does the specification contemplate a patient population consisting of subjects at risk of developing cirrhosis. The claims are not supported by the original disclosure because they are directed to treating a particular set of patients that is not described, either implicitly or explicitly, in the originally filed specification and claims. Therefore, claims directed to treating a subject at risk of developing cirrhosis of the liver constitute new matter.

Claims 65-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to a method of treating a subject at risk of developing cirrhosis of the liver wherein the method steps set forth treat the risk of developing cirrhosis of the liver. The specification does not define what constitutes treating the risk of developing cirrhosis. With regard to treatment of patients that are not already diagnosed as having cirrhosis of the liver, the only outcome contemplated is prevention. Thus, it would seem that the claims directed to treating a subject at risk of developing cirrhosis of the liver encompass, at least in part, methods of preventing cirrhosis. For reasons set forth in the 2 June Office Action, the specification does not provide enablement for preventing cirrhosis of the liver.

To summarize, although the relative level of skill in the art is high, the skilled artisan would not expect to be able to prevent the development of cirrhosis using the instant claimed method without additionally removing the underlying cause of the liver disease. There is nothing in the art to suggest that merely increasing liver cell proliferation according to the disclosed method would prevent the development of cirrhosis resulting from any conditions. As the claims encompass a method of preventing liver cirrhosis regardless of the etiology of the disease, the skilled artisan must extend the teachings of the specification, which are limited to a method of increasing the efficiency of transfection of liver cells *in vivo* and a recitation of HGF as one of many possible proteins that could be expressed in the liver, such that development of cirrhosis can be prevented regardless of whether the disease is a result of viral infection, alcoholism or

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other drug abuse, biliary obstruction, porphyria, albetalipoproteinaemia, glycogen storage diseases, Wilson's disease, sarcoidosis, syphilis, or veno-occlusive disease among others. As the art teaches each of these diseases is likely to have its own set of obstacles to effectively preventing the development of cirrhosis (see the 2 June Office Action, pages 5-6), the skilled artisan is left to address each of these obstacles without any guidance from the Inventor as to how to proceed. Thus, the skilled artisan could not practice the claimed invention without first engaging in blind trial and error experimentation to identify the method steps that must be added to those set forth in the claims so that the method can be used according to its stated purpose. Clearly, this would require that the skilled artisan seeking to practice the claimed subject matter engage in undue experimentation.

Thus, for reasons of record, claims 66-68 are rejected under 35 U.S.C. §112, first paragraph, as lacking an enabling disclosure.

Allowable Subject Matter

Claims 51-65 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

DMS

Anne-Marie Falk
ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER